

IMPLANTABLE PERCUTANEOUS STIMULATION LEAD WITH LEAD CARRIER

CROSS-REFERENCE

- [01] This disclosure is related to the following co-pending applications entitled "Implantable Percutaneous Stimulation Lead With Interlocking Elements" by inventors Vinup et al., Attorney Docket No. P10259.00 filed on September 20, 2001, "Surgical Lead Body" by inventor Cross, Serial No. 09/500,201 filed February 8, 2000, "Apparatus And Method For Percutaneous Implant Of A Paddle Style Lead" by Redko et al., Serial No. 09/302,694 filed April 30, 1999, which are not admitted as prior art with respect to the present disclosure by its mention in this section.

FIELD OF THE INVENTION

- [02] This invention relates to a medical device and more particularly to a neurological stimulation lead that can be implanted in a human body.

BACKGROUND OF THE INVENTION

- [03] The medical device industry produces a wide variety of electronic and mechanical devices such as neurological stimulators, therapeutic substance infusion pumps, pacemakers, and defibrillators for treating patient medical conditions such as pain, movement disorders, functional disorders, spasticity, cancer, and cardiac disorders. Medical devices can be configured to be surgically implanted or connected externally to the patient receiving treatment and can be used either alone or in combination with pharmaceutical therapies and surgery to treat patient medical conditions. For certain medical conditions, medical devices provide the best and sometimes the only therapy to restore an individual to a more healthful condition and a fuller life. One type of medical device is an implantable neurological stimulation system which typically includes a neurostimulator, an electrical stimulation lead, and an extension such as shown in Medtronic, Inc. brochure "Implantable Neurostimulation System" (1998). An implantable neurological stimulation system delivers electrical pulses to tissue such as neurological tissue or muscle to treat a medical condition.

[04] One application of neurological stimulation systems is for spinal cord stimulation (SCS) to treat chronic pain. In many cases, the leads used for SCS are implanted percutaneously, through a large needle inserted into the epidural space. When a percutaneous lead is used for SCS, there can be undesirable current flow into areas of the patient's anatomy away from the spinal cord, because the electrodes typically cover the circumference of the stimulation lead. Additionally, dual percutaneous lead implants are becoming more common in the clinical practice of SCS. Currently, most dual lead systems are implanted as two individual single lead implants (i.e., two separate needle sticks, two separate lead insertions). Implanting dual leads in this way makes it difficult to control the relative position of the two leads with respect to one another. Currently, the physician typically uses fluoroscopy to determine the relative position of the two leads, and must try to assure that the leads do not touch (leading to a potential short between electrodes) and also that the leads are not too far apart (resulting in less than optimal stimulation). To prevent shorting, one approach has been to stagger the electrode contacts, rather than placing them adjacent on the parallel leads. In addition to being difficult to position at the time of implant, once the leads are permanently implanted, there is no guarantee that the leads will not move relative to one another (i.e., migrate) potentially reducing therapy efficacy.

[05] For the foregoing reasons, what is needed is an electrode shield that can be attached to a stimulation lead to limit current flow to a selected area around the electrode, and a means for coupling more than one lead together in a controlled fashion.

BRIEF SUMMARY OF THE INVENTION

[06] An implantable neurological stimulation lead with lead carrier has a lead carrier with an attachment detail for coupling to a first lead body first distal end and an electrode shield to insulate a portion of the electrode. The first lead body has an outer body, a first distal end, and a first proximal end. The first lead body includes at least one electrode carried on the first distal end, at least one electrical connector carried on the first proximal end, and at least one conductor electrically connecting the electrode to the electrical connector and insulated by the lead body. The implantable neurological stimulation lead with lead carrier has many embodiments and methods of operation.

BRIEF DESCRIPTION OF THE DRAWINGS

- [07] FIG. 1 shows a neurological stimulation system environment embodiment;
- [08] FIG. 2a shows a lead carrier configured for a single stimulation lead having a single lead clip embodiment;
- [09] FIG. 2b shows a cross-section of FIG. 2a;
- [10] FIG. 3a shows a lead carrier configured for a single stimulation lead having a single lead ring embodiment;
- [11] FIG. 3b shows a cross-section of FIG. 3a;
- [12] FIG. 4a shows a lead carrier configured for two stimulation leads having a dual medical clip embodiment;
- [13] FIG. 4b shows a cross-section of FIG. 4a;
- [14] FIG. 5a shows a lead carrier configured for two stimulation leads having a dual lead clip embodiment;
- [15] FIG. 5b shows a cross-section of FIG. 5a;
- [16] FIG. 6a shows a lead carrier configured for two stimulation leads having a dual lead sleeve embodiment;
- [17] FIG. 6b shows a cross-section of FIG. 6a;
- [18] FIG. 7a (prior art) shows a example of an electrical field of a percutaneous stimulation lead;
- [19] FIG. 7b shows a prophetic example of an electrical field of a percutaneous lead with a lead carrier embodiment; and,
- [20] FIG. 8 shows a flow chart of a method for attaching a lead carrier to a neurological stimulation lead embodiment.

DETAILED DESCRIPTION OF THE INVENTION

[21] FIG. 1 shows an environment of an implantable neurological stimulation system 20. The implantable neurological stimulation system 20 comprises an implantable neurological stimulator 22, a stimulation lead with lead carrier 23, a first lead body 24, and a second lead body 26. The implantable neurological stimulator 22 provides a programmable stimulation signal that is delivered to a desired location or target to stimulate selected nerves or muscle tissue. The implantable neurological stimulator 22 is typically implanted in a subcutaneous pocket around the upper buttocks sometime after the stimulation lead has been implanted and its effectiveness verified. The implantable percutaneous stimulation lead with lead carrier would be particularly relevant for spinal cord stimulation therapies to treat pain. For a spinal cord therapy the implantable percutaneous stimulation lead with lead carrier would typically be inserted into the epidural space through a large gauge epidural needle.

[22] FIG. 2a shows a lead carrier configured for a single stimulation lead having a single lead clip embodiment, and FIG. 2b shows a cross-section of FIG. 2a. FIG. 3a shows a lead carrier configured for a single stimulation lead having a single lead ring embodiment, and FIG. 3b shows a cross-section of FIG. 3a. The implantable neurological stimulation lead with lead carrier comprises a first lead body 24 and a lead carrier 25. The first lead body 24 has an outer body 28, a first distal end 30, and a first proximal end 32, at least one electrode 34, at least one electrical connector 36, and at least one conductor 38. The outer body 28 is manufactured from a material that is biocompatible and electrically insulating. The electrode 34 is carried on the first distal end 30. The electrode 34 can be configured as a ring or any portion of a ring to include a substantially flat electrode. The electrical connector 36 is carried on the first proximal end 32. The conductor 38 electrically connects the electrode 34 to the connector 36 and is insulated by the outer body 28.

[23] The lead carrier 25 has an attachment detail 27 for coupling to the lead distal end and an electrode shield 29 to insulate a portion of the electrode. The attachment detail 27 can be a wide variety of geometries that are capable of fastening to a stimulation lead 23 such as a clip, a ring, a sleeve, and the like. The attachment detail 27 would typically be positioned either medially or dorsally on the first lead body 24. In some embodiments, more than one

attachment detail 27 can be used along the first lead body 24 to position the electrode shield 29.

[24] The electrode shield 29 would typically be configured to cover the dorsal, medial, or lateral sides, or portions thereof, of the electrodes 34. When configured to cover the dorsal side of the electrodes 34, the electrode shield 29 embodiment could minimize or prevent the flow of electrical current toward dorsal ligament structures in the spine that are believed to cause pain and limit the useful stimulation signal magnitude. When configured to cover the lateral side of the electrodes 34, the electrode shield 29 embodiment could minimize or prevent the flow of electrical current laterally toward the dorsal roots. The electrode shield 29 can be manufactured from a wide range of biocompatible insulators such as a polymer and the like.

[25] FIG. 4a shows a lead carrier configured for two stimulation leads having a dual medial clip embodiment, and FIG. 4b shows a cross-section of FIG. 4a. FIG. 5a shows a lead carrier configured for two stimulation leads having a dual dorsal clip embodiment, and FIG. 5b shows a cross-section of FIG. 5a. FIG. 6a shows a lead carrier configured for two stimulation leads having a dual lead sleeve embodiment, and FIG. 6b shows a cross-section of FIG. 6a. The second lead body 26 has a outer body 28, a second distal end 42, and a second proximal end 44, at least one electrode 34, at least one electrical connector 36, and at least one conductor 38. The outer body 28 is manufactured from a material that is biocompatible and electrically insulating. The electrode 34 is carried on the second distal end 42. The electrode 34 can be configured as a ring or any portion of a ring to include a substantially flat electrode 34. The electrical connector 36 is carried on the second proximal end 44. The conductor 38 electrically connects the electrode 34 to the connector 36 and is insulated by the outer body 28. In addition to the first lead body 24 and the second lead body 26, there can be a third lead body, a forth lead body and so on.

[26] The lead carrier 24 when configured for more than one stimulation lead would typically use more than one attachment detail 27. The attachment details 27 can be configured to provide for desired spacing between first lead body 24 electrodes 34 and second lead body 26 electrodes 34 such as in the range from about 0.5 mm (0.0197 inches) to about 2.5 mm (0.0985 inches). A clinician could use various attachment details 27 to configure lead body spacing according to the clinician's preference or according to the patient's anatomy.

[27] FIG. 7a (prior art) shows an example of an electrical field of a percutaneous stimulation lead, and FIG. 7b shows a prophetic example of an electrical field of a percutaneous lead with a lead carrier embodiment. In FIG. 7a, the electrical field 46 surrounding a ring electrode 34 on a neurological stimulation lead is relatively symmetric. FIG. 7b shows how the electrical field 46 surrounding an electrode 34 is believed to be influenced by the electrode shield 29. It is believed that the electrical field 46 in FIG. 7b is similar to the electrical field 46 that can be found in a surgical paddle lead such as a Medtronic Specify lead.

[28] FIG. 8 shows a method embodiment for attaching a lead carrier 25 to a neurological stimulation lead. The method comprises aligning 48 a first lead body 24 in a lead carrier 25. The first lead body 24 is then inserted 50 in an attachment detail 27 of the lead carrier 25 and securely fixed to the lead carrier 25. The first lead body 24 electrode 34 is then positioned 52 in relation to the electrode shield 29 to obtain the desired shielding of the electrode 34 by the insulative electrode shield 29. A second lead body 26 is aligned 54 in the lead carrier 25. The second lead body 26 is inserted 56 in an attachment detail 27 of the lead carrier 25. The second lead body 26 electrode 34 is positioned 58 in relation to the electrode shield 29 to obtain the desired shielding of the electrode 34 by the insulative electrode shield 29. In some embodiments the first lead body 24 electrode 34 is then positioned in relation to the second lead body 26 electrode 34.

[29] Thus, embodiments of the implantable neurological stimulation lead with lead carrier 23 are disclosed. One skilled in the art will appreciate that the present invention can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation, and the present invention is limited only by the claims that follow.